REMARKS

Claims 1 and 19 have been amended. The instant amendment finds support throughout the specification and the claims as originally filed. For example, paragraphs [0072]-[0076] of the specification describe substantially purifying antibody fragments from a cell media. As such, no new matter has been added.

Rejection of Claims 1-3, 5-11, 13-23 and 25 Under 35 U.S.C. § 112 ¶1 - Enablement

The Examiner has rejected Claims 1-3, 5-11, 13-23, and 25 under 35 U.S.C. § 112, first paragraph, as not enabled by the specification. The Examiner asserts that the specification does not reasonably provide enablement for culturing antibody-producing cells in a culture medium adjusted to about pH 3.5 and/or changed to any temperature in order to produce antibody fragments without affecting cell viability or the ability of the cells to produce antibody. Applicants respectfully submit that in light of the amendments to the claims, the Examiner's rejection is overcome.

Independent Claims 1 and 19 have been amended to recite "incubating said cell line under conditions to express recombinant antibody into said cell media." Claim 1 has been further amended to recite that the cell media is incubated under adjusted pH conditions to facilitate cleavage of the antibodies to clarify that the cell media contains recombinant antibodies before it is subject to pH modifications aimed at producing antibody binding fragments. Accordingly, viability of the cell line as a result of the pH and/or temperature modifications is not required since the antibodies are already in the media when the recited pH changes occur.

The Examiner concedes that the specification is "enabling for generating antibody fragments in conditioned, cell cultured media or supernatant from antibody-producing cells by adjusting pH and temperature of the media." (Office Action at 4) Because the claims, as amended, recite methods of generating antibody fragments in conditioned, cell cultured media by adjusting pH and temperature, Applicant respectfully submits that the claims are fully enabled by the specification. Applicant respectfully requests withdrawal of the Examiner's rejection under 35 U.S.C. §112, paragraph 1 and respectfully submit that the application is in condition for allowance.

van Erp Does Not Anticipate The Amended Claims

To be anticipatory under 35 U.S.C. § 102, a reference must teach each and every element of the claimed invention. *See Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1379 (Fed. Cir. 1986). Applicant respectfully submits that van Erp does not teach each and every element of Claims 1 and 19, as amended.

Claim 1, as amended, recites "substantially purifying said antigen-binding antibody fragments." van Erp does not disclose purifying antigen-binding antibody fragments resulting from the degradation of monoclonal antibodies in culture. van Erp's purpose in purifying protetolytic enzymes is to devise a strategy to inhibit protease cleavage of the antibodies in the cell media. van Erp describes the protease cleavage that occurs as "degradation" of the "mAbs produced by hybridomas." The cleaved antibody fragments disclosed in van Erp thus represent the result of a harmful degradation process the researchers aim to curb. For this reason, van Erp does not disclose purifying these fragments from the cell media. Further, one skilled in the art reading van Erp would not modify the reference to purify these fragments as the reference clearly teaches away from the value of these fragments.

Moreover, there is no teaching or disclosure that the fragments produced from van Erp's degradation process are capable of binding an antigen. There are no experiments, qualitative analyses, or even postulations that the fragments produced retain their ability to bind antigen, as recited in Claim 1. Accordingly, Claim 1, as amended, is not anticipated by van Erp.

Further, Claim 19 is not anticipated by van Erp. Claim 19 recites a method for producing antigen-binding $F(ab')_2$ fragments comprising the steps of inactivating endogenous cysteinyl enzymes while activating endogenous aspartyl enzymes. The van Erp reference fails to teach a method of proteolysis involving the activation of one enzyme and the inactivation of a different enzyme. Accordingly, van Erp fails to teach each and every element of Claim 19.

All pending claims depend either from independent Claim 1 or 19. As dependent claims by definition are narrower in scope than the independent claim from which they depend, a finding of novelty for Claims 1 and 19 is necessarily a finding of novelty for the narrower dependent claims.

For all the above reasons, Applicant respectfully submits that van Erp et al., do not teach each and every element of the claimed invention. Applicants respectfully submit that the application is in condition for allowance.

No Disclaimers or Disavowals

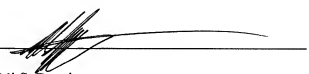
Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, the Applicants are not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. The Applicants reserve the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that the Applicants have made any disclaimers or disavowals of any subject matter supported by the present application.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: 10/31/2008

By: 

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AMEND

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